

### REMARKS

Claims 1-3, 8-21, and 24-27 are presented for the Examiner's review and consideration. In this Response, Applicant has amended claims 1-3, 8-21 and 24-25, and added claims 26-27. Applicant believes that the claim amendments and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicant respectfully submits that that they do not limit the range of any permissible equivalents.

#### 35 U.S.C. § 103

Claims 1-3 and 8-11, and 12-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,540,718 to Bartlett ("Bartlett") in view of U.S. Patent No. 4,235,238 to Ogiu et al. ("Ogiu"). Claims 24-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,540,718 to Bartlett ("Bartlett") in view of U.S. Patent No. 4,235,238 to Ogiu et al. ("Ogiu"), and U.S. Patent No. 6,106,545 to Egan. For the reasons set forth below, Applicant respectfully submits that the rejected claims are patentable over the references cited.

#### Bartlett

Bartlett discloses a substantially conical suture anchor having a bore in which an end of an insertion tool is inserted. (Abstract). A patient bone hole 70 has already been drilled into patient bone 72. (Col. 6, lns. 64-65). It will be understood that any insertion tool with a shape memory insertion end may be used in the preferred insertion method. Moreover, any suitable substantially rigid anchor with a bore for the insertion tool may be used. (Col. 7, lns. 2-6). Bore 34 is preferably drilled parallel to base 28. (Col. 7, lns. 14-15).

Any suitable means for attaching the suture to the suture anchor may be used within the scope of the invention. (Col. 6, lns. 34-35). Suture 64 may be threaded through bore 34 of the suture anchor in any preferred manner, such as those illustrated in FIGS. 6-8. In FIG. 6, one end of suture 64 is threaded through bore 34 and looped around the conical surface of suture anchor

20 adjacent leading edge 30. (Id). Thus, suture 64 passes through suture anchor 20 only once, as thread through the eye of a needle. (Id).

Typically, insertion end 44 is bent to the greatest extent immediately before trailing edge 32 leaves the portion of patient bone hole 70 in patient cortical bone tissue 74, as shown in FIG. 12. (Col. 7, lns. 34-37). Once trailing edge 32 begins travelling through patient cancellous bone tissue 76, insertion end 44 begins to resume its initially straight configuration, as shown in FIGS. 13 and 14. (Id). Preferably main body 42 of insertion tool 40 is not as flexible as insertion end 44, and remains straight throughout the insertion procedure. (Id). As best seen in FIG. 14, as suture anchor 20 travels deeper into patient bone 72, right trailing edge 32 travels further, and the greater influence the insertion tool's shape memory has over the configuration of insertion end 44. (Id). Once apex 24 has cleared patient cortical bone tissue 74, and the entire suture anchor is in cancellous bone tissue 76, insertion end 44 of insertion tool 40 is free to return to its original configuration, as shown in FIG. 15. (Id). The pointed apex 24 allows suture anchor 20 to travel counterclockwise, easily cutting through cancellous bone tissue 76. (Id).

Thus, in Bartlett, a suture anchor is passed through a predrilled hole, and is oriented through attachment to a tool which has a shape memory alloy insertion end. The insertion end of the tool passes through a bore, and a suture passes through a single additional bore. Functioning as a spring, the alloy tip serves to reconfigure the anchor after it has passed through the cortical bone. The tip is pointed in order to cut through cancellous bone.

As such, Bartlett fails, at least, to disclose two passages orthogonal or transverse to the longitudinal axis (Fig. 9 et seq.), a plurality of passages for threading suture, and using a suture section under tension to rotate the anchor. With respect to claim 9, Bartlett further fails to disclose a cylindrical body, piercing body tissue with an anchor, and two suture sections extending from two passages, where one suture section is tensioned, and the other is relaxed.

Ogiu

Ogiu discloses a coeliac tissue-suturing apparatus in which a needle is conducted through an endoscope into a body cavity to suture a broad coeliac bleeding spot... (Col. 1, lns. 39-41). [The] end of a suturing thread 9 extended along the peripheral surface of the tubular member 1 which faces the needle 3 is fastened to a first pillar like or cylindrical stop 7 in a state inserted into an annular groove 8 formed at the center of the first stop 7. (Col. 3, lns. 60-64). The first stop 7 is received in the receiving chamber 6, such that the rear end of the stop 7 is inserted into the passage 10, thereby preventing the stop 7 from naturally coming off. (Id). When the suturing operation is brought to an end, the suturing apparatus is taken out of the body cavity together with an endoscope. (Col. 5, lns. 3-6).

Thus, Ogiu discloses a surgical instrument, or tool, which inserts a “stop”. The stop is used to prevent a suture from pulling through tissue (see figures of Ogiu). In one embodiment, a suture passes around an annular groove at the center of the stop, and in another, the stop has a single bore (Fig. 51 et seq.).

As such, Ogiu does not show an implant with more than one passage for threading suture. The tool is not an implant, in that it does not secure body tissue, but rather installs a device used to secure body tissue. The tool itself is removed from the body completely. The device which secures body tissue, the “stop”, is rotated by the body of the tool, and not by the sutures. With respect to claim 9, Ogiu further fails to disclose piercing body tissue with an implant, and two suture sections extending from two passages, where one suture section is tensioned, and the other is relaxed.

In contrast, in the present invention, an anchor 20 is formed of a single piece of bone and includes a cylindrical body portion 22 and a pointed end portion 24. (§[0030]). The pointed end portion 24 has a conical configuration. (Id). The cylindrical body portion 22 and pointed end portion 24 have a common longitudinal central axis 28 which extends axially through the anchor 20. (Id).

It is contemplated that the anchor 20 may be used in association with a suture. ([0032]). If and when the anchor 20 is to be used with a suture, the anchor is provided with a pair of passages 30 and 32. (Id). The passages 30 and 32 have a cylindrical configuration and extend diametrically through the cylindrical body portion 22. (Id). Central axes of the passages 30 and 32 extend parallel to each other and intersect the central axis 28 of the anchor 20. (Id).

The passage 30 is formed entirely in the body section 22. ([0033]). However, the passage 32 is formed partially in the body section 22 and partially in the pointed end portion 34. (Id). Thus, the major portion of the passage 32 is formed in the body portion 22. (Id). However, a minor portion of the passage 32 extends into the pointed end portion 24. (Id).

When the tissue 40 is to be connected with the bone 44, the anchor 20 is utilized to initiate the formation of an opening in the bone at a location which is free of naturally occurring openings. ([0046]).

When the anchor has moved through a predetermined distance into the cancellous bone 66, the anchor is pivoted from the orientation illustrated in Fig. 3 to the orientation illustrated in Fig. 4. ([0057]). To initiate the toggling action, a section 70 of the suture 36 extending through the anchor passage 32 to a location outside of the bone is tensioned. ([0058]). At this time, a second section 72, which extends through the anchor passage 30, is relaxed. (Id).

As such, the present invention discloses an implant having a pointed end portion. A suture passes through two passages, one proximate the pointed portion. After passing through body tissue, the implant is rotated so that it cannot pull free of the hole into which it has been passed. The rotation is accomplished by tensioning the suture section extending from the passage proximate the pointed top, while relaxing the section of suture passing through the other passage in the implant body.

The rejection states that Bartlett discloses a plurality of openings each defining a passage through the body portion orthogonal or transverse to the longitudinal central axis, citing Fig. 1A and Col. 5, lines 34-37. Applicant respectfully does not agree that Fig. 1A is illustrative of this

recitation, as there is only a single passage shown. With respect to the cited text, Bartlett therein recites "...a figure eight (thereby providing separate bores for the suture and the insertion tool)...". While a figure eight is not illustrated, Fig. 9 et seq. does appear to show two bores. However, of the two bores shown, the tool bore, at least, is not orthogonal or transverse to the longitudinal central axis. In addition, only a single bore is disclosed as providing a passage for a suture.

Thus, Applicant respectfully submits that Bartlett does not disclose the claimed recitations, among others, of two passages for sutures, and rotating the anchor by tensioning one of the sutures. With respect to claim 9, Bartlett further fails to disclose a cylindrical body, piercing body tissue with the anchor, and two suture sections extending from two passages, where one suture section is tensioned, and the other is relaxed.

Further, Applicant respectfully acknowledges the rationale stated in the rejection for combining Bartlett and Ogiu. However, Applicant respectfully maintains that it would not be obvious to combine a tool which is removed, with an implant which remains in connection with body tissue. In addition, the combination would not work, since the tool does not actually hold tissue together, but rather is used to install an anchor, termed a "stop" in Ogiu, which is used to hold tissue together. Notwithstanding the above, Applicant has amended the claims to positively recite an implant, and thus the tool of Ogiu cannot be applied to supply the claimed elements.

Thus, Applicant submits that only the "stop" in Ogiu could logically be combined with Bartlett. As the suture anchor of Ogiu has only a single passage, and rotation is performed by a tool bore, Ogiu does not provide at least these elements missing in Bartlett, and therefore the combination fails to disclose or suggest the claimed invention.

Claim 1 recites, *inter alia*, an implant comprising a pointed end, a plurality of passages for threading suture, and a suture section threaded through a passage proximate the pointed end, operative to rotate the implant when the suture section is tensioned. Claim 9 recites, *inter alia*, an implant comprising a cylindrical body and a pointed end operative to pierce body tissue, first and second passages having first and second suture sections that extend away from the first and

second passages, wherein the implant is rotated when the first suture section is tensioned and the second suture section is relaxed. Thus, these and other amendments presented patentably distinguish the claimed implant from the anchor of Bartlett, and the installation tool and “stop” of Ogiu.

Accordingly, Applicant submits that claims 1 and 9 are patentable over Bartlett in view of Ogiu. As claims 2-3 and 8 depend from claim 1, and claims 10-20 depend from claim 9, these dependent claims necessarily include all the limitations of their base claim. Accordingly, applicant respectfully submits that the dependent claims are allowable over Bartlett in view of Ogiu for the same reasons.

Independent claims 21 and 24 contain recitations similar to those in claims 1 and 9. Claim 21 recites, *inter alia*, an implant comprising a cylindrical body made of bone, including a conical end portion, a first passage proximate the conical end portion, a second passage disposed further from the conical end portion, and a suture section threaded through the first passage operative to initiate rotation of the anchor. Claim 24 recites, *inter alia*, an implant assembly comprising a cylindrical body defining a pointed end portion, a first passage proximate the pointed end, a second passage, a suture connected under tension and extending through the first and second passages, and a retainer for maintaining the tension in the suture.

Accordingly, the arguments made above apply equally to claims 21 and 24. A distinction is noted with respect to claim 24, in that the anchor is not rotated by tension on a suture. Applicant submits, however, that the remaining claim elements, as recited above, render the claim patentable over the cited references. Claim 24 adds the further recitation of a retainer for maintaining tension in the suture, which further distinguishes the claim over the prior art. Thus, Applicant submits that claims 21 and 24 are patentable over Bartlett in view of Ogiu.

As claim 25 depends from claim 24, this dependent claim necessarily includes all the limitations of its base claim. Accordingly, applicant respectfully submits that dependent claim 25 is allowable over Bartlett in view of Ogiu for the same reasons.

Applicant: Peter M. Bonutti  
Application No.: 10/614,352  
Examiner: D. Yabut

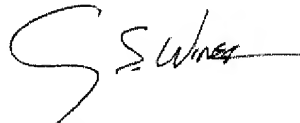
In light of the foregoing, Applicant request reconsideration and withdrawal of the section 103 rejections.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$50 is believed to be due for two additional dependent claims. However, please charge the required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-003-1).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "G S Winer", with a long horizontal stroke extending to the right.

Gary S. Winer, Reg. # 31,806  
for Paul D. Bianco, Reg. # 43,500

Customer Number: 33771  
Paul D. Bianco  
FLEIT KAIN GIBBONS GUTMAN BONGINI & BIANCO  
21355 East Dixie Highway  
Miami, Florida 33180  
Tel: 305-830-2600; Fax: 305-830-2605  
e-mail: [pbianco@focusonip.com](mailto:pbianco@focusonip.com)